PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Robert Michael Roberts *et al.*

Serial No.: 10/655,547

Filed: September 4, 2003

For: COMPOSITIONS AND METHODS FOR EARLY PREGNANCY DIAGNOSIS

Group Art Unit: 1641

Examiner: Cheu, Changwa

Atty. Dkt. No.: UVMO:003USC1

CERTIFICATE OF MAILING
37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date below.

03/02/05
Date

Robert E. Hanson

DECLARATION OF JONATHAN A. GREEN UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

I, JONATHAN A. GREEN, HEREBY DECLARE AS FOLLOWS:

1. I am a co-inventor of the subject matter disclosed and claimed in the above-referenced patent application.

2. I am currently employed by The University of Missouri as an Assistant Professor. I hold a Ph.D. in Biochemistry from the University of Missouri. I have been conducting research in the area of biochemistry and reproductive biology since 1991.

3. I understand that the Patent and Trademark Office Examiner in charge of assessing the patentability of the referenced patent application has asserted that the specification does not teach

methods for the identification of all of the bovine pregnancy-associated antigens (PAGs) encompassed by the claims.

4. I am providing the present Declaration to submit further evidence that the specification teaches those of ordinary skill in biochemistry and reproductive biology how to make and use the full scope of PAGs that are present early in pregnancy and absent about two months post-partum without undue experimentation.

5. I understand that the present claims are directed to a method for detecting pregnancy in a bovine animal comprising, obtaining a sample from said animal; and detecting at least one pregnancy associated antigen (PAG) in the sample that is present early in pregnancy and is undetectable at about two months post-partum; whereby detection of the PAG indicates that the animal is pregnant.

6. By following the teachings of the present patent application, a person of ordinary skill in biochemistry and reproductive biology would be able to isolate and identify PAGs in addition to PAGs 4, 6, 7, 16, 17, 20, and 21 that are present early in pregnancy and undetectable at about two months post-partum using only routine screening techniques. One approach taught by the present specification that may be used in this to isolate and identify additional PAGs encompassed by the claims is to clone PAGs by cDNA library screening or RT-PCR from mRNA obtained from early-pregnancy placentas (Specification, p. 58, ln. 4 – p. 59, ln. 7). The present patent application provides numerous PAG-encoding sequences and fragments thereof that are useful for screening in this regard for identifying related PAGs (*see e.g.*, SEQ ID NOs: 2, 4, 5, 6, 7, and 9). The specification teaches that these sequences can be used to screen cDNA libraries or RNA for related genes (Specification, p. 41, ln. 25 – p. 42, ln. 2; p. 58, ln. 4 – p. 59, ln. 7). The resulting cDNAs may be translated and the polypeptides used for antibody production as taught by the specification at page 42, lines 19-21. The monoclonal or polyclonal antibodies are then used to screen serum or other biological fluids to identify the PAGs that are detectable early in pregnancy and undetectable at about two months post-partum. The present application describes

methods for the immunological detection of pregnancy at, for example, page 50, line 11 to page 55, line 27.

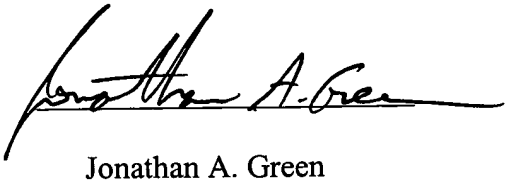
7. Another approach taught by the application for isolating and identifying additional PAGs encompassed by the claims is to employ an antibody to a known PAG. As described in the application, an anti-PAG antibody may be used in an antibody cloning protocol to obtain cDNA or genes encoding other PAG polypeptides (p. 46, ln. 2-12). The resulting cDNAs are translated and the recombinant proteins used for antibody production as taught by the specification at page 42, lines 19-21. The monoclonal or polyclonal antibodies are then used to screen serum or other biological fluids to identify the PAGs that are detectable early in pregnancy and undetectable at about two months post-partum. The present application describes methods for the immunological detection of pregnancy at, for example, page 50, line 11 to page 55, line 27.

8. In conclusion, by following the teachings of the present specification as outlined in either of Paragraphs 6 or 7, a person of standard skill in biochemistry and reproductive biology would be able to identify additional bovine PAGs that are detectable early in pregnancy and undetectable about two months post-partum using only routine screening methods.

9. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

28 February, 2005

Date



Jonathan A. Green